K092583

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12. Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

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JAN 13 2010

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Date Prepared: August 19, 2009

B. Device Identification

Classification Name: Laser, Fluorescence Caries Detection

Common Usual Name: DENTAL FLUORESCENCE EXAMINATION DEVICE

Proprietary Name: SOPROLIFE

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
INSPEKTOR PRO	INSPEKTOR Dental Care BV	K040063	June 24, 2004
SOPRO 595	SOPRO	K012505	October 5, 2001

The SOPROLIFE is substantially equivalent to the predicate device by INSPEKTOR DENTAL CARE BV, the INSPEKTOR PRO (K040063), and to the predicate device by SOPRO, the SOPRO 595 (K012505), which both have been previously cleared by the FDA and currently being marketed.

D. Device Description

The SOPROLIFE is a fluorescence caries detection device . This device is a fluorescence detector housed in a dental handpiece, and a control unit that performs device calibration, as well as variable tone emitting and fluorescence measurement functions.
The handpiece can be connected with 5 different control units : Dock M_VIDEO Dock M_USB2, Dock MU_VIDEO, Dock MU_USB2, Dock USB2.

The SOPROLIFE is a device used in clinical dental applications to observe the condition of hard dentinal tissues.
As the SOPROLIFE can be adapted to the most complex of clinical situations, it quickly helps the dentist to get a complete analysis as it adjusts treatment options in Diagnosis aid mode. In Treatment aid mode, the SOPROLIFE facilitates observation of the dentinal tissue condition in progress and at the end of the treatment. In daylight mode the SOPROLIFE enables the dentist to visualize anatomical details invisible to the naked eye or with mirror like an intra oral camera SOPRO 595.

E. Intended Use

This SOPRO product is intended to be used by qualified physicians in dentistry as an aid in the diagnosis of dental caries, and as an intra oral camera to visualize anatomical details invisible to the naked eye or with a mirror

F. Indications for use
The SOPROLIFE is indicated as an aid in the diagnosis of dental caries and as an intra oral camera to visualize anatomical details invisible to the naked eye or with mirror.

G. Substantial Equivalence

The SOPROLIFE (in Diagnosis aid mode and in Treatment aid mode) and the predicate device, INSPEKTOR PRO (K040063), are both fluorescence caries detection device for use in dentistry by qualified physicians, to aid in the diagnosis of dental caries by measuring increased induced fluorescence.
The SOPROLIFE (in Daylight mode) and the predicate device SOPRO 595 (K012505) are both intra oral camera to visualize anatomical details invisible to the naked eye or with mirror.
Differences that exist between the SOPROLIFE and the predicate devices relating to technical specifications and performances are minor and do not affect the safety and effectiveness of the SOPROLIFE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

SOPRO
C/O Mr. Rick Rosati
Quality Manager
Acteon, Incorporated
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

JAN 13 2010

Re: K092583
Trade/Device Name: SOPROLIFE
Regulation Number: 21CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: January 7, 2010
Received: January 8, 2010

Dear Mr. Rosati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number :

Device Name: SOPROLIFE

Indications For Use :

The SOPROLIFE is indicated as an aid in the diagnosis of dental caries and as an intra oral camera to visualize anatomical details invisible to the naked eye or with mirror.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Hyley for HSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092583